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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478
28596 7590 05/07/2007 GORE ENTERPRISE HOLDINGS, INC. 551 PAPER MILL ROAD P. O. BOX 9206 NEWARK, DE 19714-9206			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 05/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

08/499,423

Applicant(s)

CAMPBELL ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,14-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,10,14-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/15/07 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5-7,9,10,14,17,19,20,22-31,33,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (5061276). Tu et al. disclose (col. 12, lines 20,21) a tube with an outer covering, Fig. 2. Tu also discloses the device can be used as a graft, col. 4, lines 53-55. Tu additionally discloses the tube is porous, col. 3, lines 4-6. Tu discloses the graft tube is made of polytetrafluoroethylene and has a covering of polytetrafluoroethylene, col. 5, lines 29-33. Tu et al. disclose the graft can be sutured to a conduit, col. 5, lines 55-63. Tu also discloses the graft circumference increases as a result of the blood pressure, col. 5, lines 46-48. Tu additionally discloses the tube can be expanded such that the second circumference (10mm) is at least 100% larger than the tube's original circumference (4mm) prior to the application of internal pressure, col.

Art Unit: 3738

10, lines 34-38. The polytetrafluoroethylene tube is disclosed as having a microstructure of nodes interconnected by fibrils, col. 7, lines 19-22. Tu does disclose (col. 11, lines 7-11, col. 12, lines 1-4) that the layer of ptfe film is wound onto the tube at an angle and shows (Fig. 8) helical wrapping the tube. The circumference is fully capable of being increased by inflating a balloon. Tu also discloses the tube is placed on a tapered mandrel such that it forms a tapered end with a larger circumference at one end and a smaller second circumference at an opposing end, col. 10, lines 33-35.

Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Regarding claim 27, it can be construed that an interior liner is present on the graft when multiple layers of PTFE are used, col. 3, lines 35-38.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Hughes et al. (4728328). Tu et al. is explained supra. However, Tu does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the

prosthesis of Tu et al. in a vessel such as the trachea requiring replacement to the two bronchi.

Claims 3,4,15,16,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Lee (5123917). Tu et al. is explained as before. However, Tu fails to disclose the wall thickness to be less than 0.1mm or use of a stent used to secure the graft to a conduit. Lee teaches that the thickness of the graft equal to about 0.1mm, col. 5, lines 56-59. Lee additionally teaches (col. 5, lines 25-31) a stent is used to secure a graft to a blood conduit, Figs. 1,4. Lee also teaches the stent is used to provide some stiffness to the graft to support the vessel, col. 3, lines 5-9,20-24. It would have been obvious to one of ordinary skill in the art to utilize a stent or stents as taught by Lee in the graft of Tu et al. such that it provides greater support to the vessel it is implanted in. Additionally, the use of a thickness of about 0.1mm for the wall of the graft as taught by Lee in the implant of Tu et al. provides a flexible and small profile for easier delivery to the implantation site.

Response to Arguments

Applicant's arguments filed 2/15/07 have been fully considered but they are not persuasive. Applicant argues that the covering disclosed by Tu et al. includes additional material with the polytetrafluoroethylene that is not required by Applicant's invention. It should be noted that Tu '276 discloses the invention as claimed since the language used in the claims is "comprising" and not – consisting—to exclude other materials. The fact that it includes other materials not claimed is irrelevant. In response to Applicant's

Art Unit: 3738

argument that the invention of Tu et al. does not anticipate the claims, it has been held that a claim is anticipated if each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device.

Kalman v. Kimberly-Clark Corp., 218 USPQ 789. Also, Applicant argues the Tu device is not disclosed as having a second circumference remaining "substantially unchanged" with increased internal pressure. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Additionally, Applicant argues that the Tu device is not expanded to at least 100%. However, the Examiner referred to a minimum diameter which can be 4mm disclosed by Tu and then is expanded to a possible 10mm diameter disclosed by Tu. This is clearly at least 100% of an increase. In response to applicant's argument that there is no suggestion to combine the Tu '276 and Lee '917 references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, if the wall thickness is reduced it would most likely increase the elasticity of the material or covering. If the manufacturer is concerned with elasticity, then by adding additional

Art Unit: 3738

layers will provide the same coverage desired. Tu discloses that multiple layers can be added if desired, col. 3, lines 35-41. Additionally, the modification to vary the thickness to the claimed thickness and disclosed by Lee, would not cause the invention to fail as alleged by the Applicant's argument since a stent can also be used to provide the structural support and also expansion desired.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink, reading "Brian E. Pellegrino", written in a cursive style.